10 Most Common Asked Questions

1. What is a generic approval?

   A generic approval is a final label that can be used without further authorization from FSIS. The label may have to receive sketch approval because it may bear special claims (quality, nutrient content, health, negative, geographical origin, animal production, etc.), guarantees, foreign language or nutrition facts. If the label is for a single ingredient amenable product that bears no special claims, guarantees, foreign language or nutrition facts, it is a generic approval. If the label is for an amenable multi-ingredient standardized product and bears no special claims, guarantees, foreign language or nutrition facts, the label can either be a generic approval or submitted to the Labeling Review Branch attached to a label application form.

2. What labeling records do I have to maintain?

   An establishment responsibility is to create and maintain records of final labeling, otherwise known as, generic approvals. A record of generic approval consists of the actual product's label, the product formulation, processing procedure and sketch approvals, if needed. A sketch approval is required for labeling with special claims, guarantees, foreign language or nutrition facts. In addition, a sketch approval is required for labeling of non-standardized products, e.g., "Beef Flavor" and labeling for non-amenable products, e.g., "Ostrich Jerky."

3. I just received a shipment of transferred labels from another Federal establishment. How do I apply for approval?

   Transferred labels can be used without temporary approval provided the labeling is not false or misleading with the exception of an incorrect signature line and/or incorrect establishment number. Records must be maintained by the producing company that indicates how product origin is marked on the labeling; such records are especially useful in the event of a product recall. One method of product origin labeling is to cover the existing legend with a pressure sensitive legend that bears the correct establishment number. Refer to FSIS Directive 7221.1, "Prior Labeling Approval."

   Transferred labels with inaccurate or misleading information, e.g., formulation contains ingredients not declared in the ingredients statement or labeling bears a deceptive geographic claim can not be used unless a temporary approval is granted from the Labeling Review Branch. Depending on the severity of the problem, the label may have to be corrected prior to obtaining temporary approval.

4. Can I get a temporary approval?

   Temporary approvals may be granted for a period not to exceed 180 calendar days, under the following conditions listed below (a – d). If the deficiency is not minor in nature, the label will have to be corrected prior to requesting temporary approval. Corrections to labeling may encompass covering an error with indelible ink, using a corrected pressure sensitive sticker or cutting off a portion of the label.

   a. The proposed labeling would not misrepresent the product;
   b. The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;
   c. Denial of the request would create undue economic hardship; and
   d. An unfair competitive advantage would not result from the granting of the temporary approval.

5. Can I get a temporary approval for the use of the term "new?"

   After the initial six-month period of using a label with the term "new," the company would have to apply for an extension to use the label. A six-month temporary approval would only be granted under one of four provisions located within FSIS Directive 7220.1, Policy Memo 107, "Use of 'New' and Similar Terms."

6. My plant burned down and my labeling records were destroyed. Can I get copies of my approved label applications?

   We can provide microfilmed copies of labeling records on file with us, i.e., sketch, temporary or final. However, on July 1, 1996, we stopped granting final approvals but started keeping microfilmed records of sketch approvals. We can not provide copies of the old IIC approved labels or generic approvals since those records exist in the Federal plant involved or its headquarters location.

7. How do I figure out the nutrition facts serving size for a particular product?

   The serving size is based on the edible portion of food and not on inedible components, e.g., bone, seed, shell, etc. The serving size is determined from the "Reference Amounts Customarily Consumed Per Eating Occasion – General Food Supply." The tables indicating the reference amounts customarily consumed (RACC) for various meat or poultry products are located in 9 CFR 317.312 and 381.412. Important information that also applies to determining a serving size under certain circumstances is also located in regulations 9 CFR 317.309(b) and 381.409(b), e.g., discrete units, bulk products, etc.

8. What nutrition claim size requirements do I have to follow when I am using a fanciful name in conjunction with a descriptive name?

The size of nutrient content claims can be based on a “fanciful name” or a “true product name,” with certain limitations. For example, meals and entrees often have a fanciful name to broadly identify the product which is followed by a descriptive product name. Claims can be two times the size of the largest letter in the fanciful name if the combined fanciful/true name follows the one-third sizing rule for product names. If the claims size is two times the size of the fanciful name, the size of all letters in the fanciful/true name need to be at least one-third the size of the largest letter in the fanciful/true name.

9. What can we name this product?

   Call the Labeling Review Branch and speak to a staff member. Provide a list of possible choices for a product name and provide formulation amounts and information regarding the processing procedure.

10. Am I allowed to put an ingredients statement, address line and nutrition facts on the back of a package?

    The ingredients statement, address line and nutrition facts are permitted in a location other than the principal display panel on what is referred to as an information panel. However, the ingredients statement, address line and nutrition facts must be placed together. For more details on an information panel, refer to 9 CFR 317.2(m) or 381.116(c).